

MAR 9 2007

400 Seventh Street, S.W. Washington, D.C. 20590

Pipeline and Hazardous Materials Safety Administration

Gail Ryckis-Kite
Development and Quality Manager
Saf-T-Pak
17854 - 106A Avenue
Edmonton, AB
Canada T5S 1V3

Reference No. 07-0018

Dear Ms. Ryckis-Kite:

This is in response to your January 24 and 25, 2007 e-mails to this agency concerning a final rule we issued under Docket No. PHMSA-2004-16895 (HM-226A) (6/2/06, 71 FR 32244) to revise the requirements for transporting Division 6.2 (infectious substance) materials under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) with international requirements. You note that on page 32247, Column 1, paragraph 1, of the final rule we state a Category B infectious substance packaging must be capable of passing a drop test, but not a puncture or other performance test; however, under § 173.199(a)(4) we require this packaging to be capable of passing at a height of 1.2 meters (3.9 feet) the drop and steel rod impact tests prescribed in §178.609(d) and (h), respectively. You ask if the regulatory text requiring the steel rod impact test for this packaging is an error.

The answer is yes. A packaging used to transport a Category B infectious substance must be capable of passing the drop test prescribed in § 178.609(d). The packaging is not required to also be capable of passing the steel rod impact test in § 178.609(h). We will correct this error in a future rulemaking.

I hope this information is helpful.

Sincerely,

Hattie L. Mitchell, Chief

Regulatory Review and Reinvention Office of Hazardous Materials Standards

070018

173.199(a)(4) 178.609(h)

Edmonson \$173.199 \$178.609(h) Infectious. Subtances Packaging 07-0018

From: Gail Ryckis-Kite [mailto:GailRyckisKite@saf-t-pak.com]

Sent: Thursday, January 25, 2007 5:24 PM

To: Edmonson, Eileen < PHMSA >

Subject: RE: Questions/Concerns regarding CFR173.199 Category B Packaging Requirements

Hi Elleen,

Thank you very much for your reply. We can appreciate how this may happen and look forward to seeing the correction. In the interim, our company still has a problem that maybe you can help me with, or direct me to another authority.

This test came to our attention by the US DOT Office of Hazardous Materials Enforcement. This specific test was requested to be performed on a small shipper that we provide commercially (Report Number 05435035 Supplemental). We would like to provide that office with an appropriate response that invalidates the requirement of this specific test. In addition, as a supplier of compliance training and packaging material, we do our utmost to comply to all regulations. In reaching compliance we have had to inform our customers of the regulatory text and the changes required to meet the standard. We would ask that the US Department of Transportation provide us with some sort of formal response that we may provide both to the DOT testing authority and our customers showing that this was indeed inadvertently text and compliance is not required to the steel rod impact test in 178.609(h).

Thank you again for your assistance in this matter,

## Gail Ryckis-Kite

**Development and Quality Manager** 

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1-800-814-7484

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**From:** Gail Ryckis-Kite [mailto:GailRyckisKite@saf-t-pak.com]

Sent: Wednesday, January 24, 2007 5:49 PM

To: Edmonson, Eileen < PHMSA >

Subject: Questions/Concerns regarding CFR173.199 Category B Packaging Requirements

Dear Ms. Edmonson,

I am the Development and Quality Manager at Saf-T-Pak in Edmonton Alberta Canada. This company is a certified packaging and compliance training supplier and I have some questions regarding a change in the package testing requirements for Category B infectious substances (49CFR173.199). In particular, the addition of a puncture test specified in 49CFR178.609(h).

Upon review of the Federal Register Vol. 71 No. 106 Friday June 2, 2006 I understand that the PHMSA proposed to harmonize with other requirements applicable to the transportation of Division 6.2 materials and adopt packaging requirements for Category A and Category B

infectious substances consistent with those in the UN Recommendations and ICAO Technical Instructions.

In the preamble to the Section by Section review it reads that Category B packagings must be capable of passing a drop test, but need not be capable of passing a puncture or other performance test (p. 32247), However, the amended 49CFR173.199 section specifically states that a puncture test (referenced only as 178.609(h)) must be successfully passed. Both the UN Recommendations and ICAO Technical Instructions do not place this requirement onto the Category B infectious substances packaging.

I would appreciate your advise and insight as to the distinction now placed between the requirements of Category A and Category B package testing. In addition, as this change effects the requirements for international shipments of Category B infectious substances, I would like to discuss any recommendations and insight you might provide to us regarding international shipments in and out of the USA.

This material may demand a bit of your time for review thus I submitted this email first. Unless otherwise notified I will contact you by phone tomorrow January 24, 2006 at the number listed on the report (202-366-8553). Or if you prefer I may be contacted by email or the number listed below - at your convenience.

I look forward to discussing this material with you and receiving a bit more clarification.

Kindest Regards,

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